Dear Dr. Wolfe,

The attachment contains my comments on the Talc Report.

The report has misrepresented the findings in my cited paper:

Lamm SH, MS Levine, JA Starr, and SL Tirey.
Analysis of Excess Lung Cancer Risk in Short-Term Employees.
American Journal of Epidemiology, 1988;127(6):1202-1209.

The report is also missing as a reference:

SH Lamm and JA Starr
Similarities in lung cancer and respiratory disease mortality
of Vermont and New York State talc workers.
In: Proceedings of the VIIth International Pneumoconioses Conference,
August, 1988, pp1576-1581.

Many of the concerns raised in the report about the first paper are answered in the second paper.

In summary, the report says that our study is among the strongest support evidence for the carcinogenicity of fibrous talc. Since our study, and subsequent studies of the lung cancer risks of Gouvernour Talc Company (GTC) workers, demonstrate (1) that the lung cancer risk is one of miners and not of millers whereas the high exposures are to millers and not so much miners, (2) that the risk of NYS talc workers does not differ from that of Vermont talc workers, and (3) that the lung cancer risk of GTC workers is primarily a risk primarily of short-tem workers that which they have brought with them to the GTC talc workers rather than that which they have acquired there, the studies support the lack of pulmonary carcinogenicity of GTC or non-GTC talc. Our findings do support the conclusion that talc workers acquire a risk of chronic lung disease, but they do not support the conclusion that talc workers acquire a risk of lung cancer.

Thank you,

The attachment is in Microsoft Word. Let me know if you can read it as such.

Steven H. Lamm, MD

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December 7, 2000

Attn: Mary Wolfe,PhD wolfe@NIEHS.NIH.gov
Attn: Executive Director
NTP Board of Scientific counselors

Dear NIEHS,

Re: Talc

I have today seen the draft Report on Carcinogens Background Document for Talc – Asbestiform and Non-Asbestiform. The draft background report on Talc misrepresents our publication of twelve years ago.

1. The document cites our work (Lamm et al., 1988)[1] as providing "the strongest evidence of [lung cancer mortality] risk [from talc known to have been of fibrous form].[2]

In contrast, the conclusion of our paper was that "(T)he analysis in this study suggests that the lung cancer risk demonstrated in this cohort may reflect risks acquired before this employment rather than during this employment."[3]

2. Our paper is further discussed on page 26 of the "Report". It states that "(b)ecause most workers had held previous jobs with potential exposure, the influence of prior exposure could not be meaningfully evaluated." Other than arguing about what meaningful means, this statement is incorrect.

Table 3 of that paper shows that 2.9 lung cancer cases were expected among the workers with previous jobs with prior "lung cancer risk" jobs and 2.2 lung cancers were expected among the workers without known previous jobs with prior "lung cancer risk" jobs. Nine lung cancer cases were observed among the first group, and three lung cancer cases were observed among the second, for SMRs, respectively , of 316 (p=) and 136 (p=). If the risk in the first group were the same as the risk in the second group, the expected in the first group would have been 3.95 [2.9 x 1.36 =3.95]. The lower 95% bound on an observed of nine would be 4.1. Thus, the lung cancer risk among those with prior exposure is statistically significantly greater than the lung cancer risk among those without known prior exposure. I call this meaningful.

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[1] Lamm SH, MS Levine, JA Starr, SL Tirey. Analysis of excess lung cancer risk in short term employees. Am J Epidem 1988; 127(6):1202-1209.

[2] Draft Report on Carcinogens Background Document for Talc – Asbestiform and Non-Asbestiform for the December 13-14, 2000 meeting of the NTP Board of Scientific Counselors Report on Carcinogens Subcommittee. http://roc.niehs.nih.gov/rocpublic/10pRoC/Talc/Talc.htm.
[NTP report, page 7]

[3] Lamm et al. AJE, 1988. Page 1209.

3. The description in the "Report" continues with the statement that (M)ethodological concerns with this analysis include the lack of any analysis by exposure level or latency, small numbers, and the noncomparability of SMRs from different subcohorts." This is incorrect.

The summary takes no notice of the analyses that demonstrate that the risk factors for lung cancer and for chronic lung disease in this cohort differ. History of prior exposure is a significant risk factor for lung cancer (Table 3), and the absence of prior exposure is a significant risk factor for chronic lung disease. The paper cited, in particular, states that "(T)he lung cancer mortality was found primarily among miners (nine of the 12 cases) rather than millers, although measured exposures were greater for the millers (page 1208)." The more detailed demonstration of these "lacking" analyses is found in a second paper by us that is not cited by the authors of the report. That paper is found in the published proceedings of the NIOSH-sponsored VII[th] International Pneumoconioses Conference.[4]

The second paper compares the similarities in lung cancer and respiratory disease mortality of Vermont[5] and New York State talc workers. This analysis is limited to the cohort members with at least one year of employment to make them occupationally similar to the Vermont talc workers study group. In both studies, the data have been separated for talc miners vs. talc millers. The exposure levels for these two work areas have been previously published by NIOSH and others and demonstrate (as in many other mining operations) greater exposures of millers than miners. Neither study showed an increased lung cancer risk among the talc millers. Both studies showed a four-fold risk for talc miners. Conclusions from these observations include (1) the presence of fibrous talc at the NY State plant and not at the Vermont plant has no influence on the lung cancer risk and (2) the lung cancer risk is elevated in the part of the plant with the lower exposures, not the part with the higher exposures. That is an analysis by exposure level. The table on page 1578 shows considerable comparability of SMRs across subcohorts by location and by duration. The table on page 1579 presents a latency analysis.

As indicated above, the findings of our analyses of the respiratory mortality of New York State talc workers have been described in the Report both incompletely and inaccurately. Please take this into consideration in your deliberations. If our study is indeed the strongest evidence for lung cancer mortality risk from fibrous talc, the evidence is most weak since our study concluded that there was no increased lung cancer risk from the fibrous talc.

Cordially and with thanks,

Steven H. Lamm, MD, FACOEM
President, CEOH

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[4] Lamm SH, JA Starr. Similarities in lung cancer and respiratory disease mortality of Vermont and New York State talc workers. In: Proceedings of the VIIth International Pneumoconioses Conference, August, 1988, pp1576-1581.

[5] Selevan SG, Dement JM, Waggoner JK, Froines JR.: Mortality Patterns among Miners and Millers of Non-Asbestiform Talc: Preliminary Report. J Environ Path and Tox, 1979;2:273-284.